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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,933	06/14/2006	Giuseppe Zattera	82062-0187	4073

24633 7590 08/09/2010

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EXAMINER	
PATEL, SHEFALI DILIP	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
08/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/560,933	ZATTERA, GIUSEPPE	
	Examiner	Art Unit	
	SHEFALI D. PATEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-13,15,18-21 and 24-31* is/are pending in the application.

4a) Of the above claim(s) *27-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-13,15,18-21,24-26 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. In the reply, filed on June 9, 2010, Applicant amended claims 1, 4, 12, 13, 15, 25, and 31.

2. Applicant cancelled claim 14.

3. In the non-final rejection of March 17, 2010, Examiner objected to claims 4, 12, 13, and 15 for minor informalities. Applicant amended said claims. Objection is withdrawn.

4. Examiner rejected claims 14 and 31 under 35 USC 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim subject matter. Applicant cancelled claim 14 and amended claim 31. Rejection is withdrawn.

5. Currently, claims 1-8, 10-13, 15, 18-21, 24-26, and 31 are under examination.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 25, and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In regards to claims 1, 25, and 31, the new limitation that the occluding body is in contact with the inner circumference of the main cavity "where said inner circumference of said main cavity is at its largest" appears to be new matter because the specification and drawings do not describe this feature.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-7, 12, 13, 15, 18, 20, 21, 24-26, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazee et al (US 5,908,407), and further in view of Briscoe et al (WO 99/37351) and Don Michael (US 5,163,905).

In regards to claims 1-3, 24-26, and 31, Frazee et al teaches a catheter (catheter [10]) for medical applications, suitable for being inserted into a duct comprising a first vessel (left transverse sinus [72] to right transverse sinus [74]) and a second vessel (superior sagittal sinus [56]) which branches off from said first vessel (Figure 8), the catheter [10] (Figure 4) comprising:

a. a catheter body (elongate tube [90]) which extends from a proximal end (proximal end [30]) to a distal end (distal end [32]), said catheter body [90] comprising a main cavity (through lumen [101]) having an inner circumference and a lateral wall that passes through the catheter body [90] between the proximal end [30] and the distal end [32]

(Figure 5)(column 4, lines 59-62), suitable for receiving a guide cable (guidewire [18]) for the insertion of the catheter into the first vessel (column 5, lines 20-28)(Figure 8), and at least one opening (ports [114][116][118]), disposed on the lateral wall at the distal end [32] and suitable for perfusing a substance (Figure 4)(column 5, lines 20-28), characterized in that the catheter body [90], at a portion of the lateral wall comprised between said at least one opening [114][116][118] and said distal end [32], comprises:

i. a first occluding means (occlusion balloon [41]) (Figure 4) and a second occluding means (septum valve [127]) (Figure 7), wherein the first occluding means [41] is suitable for at least partially occluding a gap between the catheter body [90] and an inner wall of the first vessel [72][74] (Figure 8), and the second occluding means contains an occluding body [127] having a radius sized so that said occluding body is in contact with the inner circumference of the main cavity [101] to prevent the flow of fluid through said main cavity (Figure 7) (column 5, lines 29-37)

b. said first [41] and second occluding means [127] defining a preferred direction of outflow (flow [62]) of said fluid from the main cavity [101] of the catheter body [90] to the second vessel [56], through said at least one opening [114][116][118] of the catheter body (Figure 8)

c. wherein each of said at least one opening [114][116][118] passes through said lateral wall and is in fluid communication with the main cavity [101] (column 5, lines 6-10)

d. said at least one opening [114][116][118] is such that the area of the at least one opening (Figure 4) is not less than the area of the cavity (at hole [125] of through lumen [101]) of the distal end [32] of the catheter body [90] (Figure 7)

Frazee et al does not teach that the occluding body [127] of the second occluding means is slideably disposed within the main cavity [101] and an insertion cable is connected to the occluding body for allowing the insertion and positioning of the occluding body within the main cavity. Briscoe et al teaches a catheter (Figures 8-13, cannula [14]), wherein an occluding body (flexible disc [108]) is slideably disposed within a main cavity (lumen [24]) and an insertion cable (elongate member [106]) is connected to the occluding body for allowing the insertion and positioning of the occluding body within the main cavity (Figures 8 and 10). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the occluding body of the second occluding means, of the catheter of Frazee et al, to be slideably disposed within the main cavity by way of an insertion cable, as taught by Briscoe et al, as as the insertion cable will allow the user the ability to control the depth of the occluding body within the catheter for preventing or allowing fluid to flow through the openings of the catheter (page 9, lines 15-30). However, neither Frazee et al nor Briscoe et al teaches that said occluding body is in contact with the inner circumference of the main cavity where said inner circumference of said main cavity is at its largest, as both Frazee et al and Briscoe et al teach an occluding body in an area of the main cavity that does not have the largest inner circumference. But whether or not the occluding body contacts the largest inner circumference of the main cavity depends upon the diameter or size and flexibility of the occluding body. Briscoe et al teaches an occluding body that is flexible such that the occluding body can pass through areas of

the main cavity having different inner circumferences (page 10, lines 1-7). Hence, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the occluding body, of the modified catheter of Frazee et al and Briscoe et al, to be larger in diameter or more flexible to contact the inner circumference of the main cavity at its largest, as a matter of obvious design choice, since modifying the size and flexibility of materials, such as occluding bodies, are well-known in the art. Furthermore, modifying the occluding body to a size and flexibility that would contact the inner circumference of the main cavity at its largest would allow for the regulation and direction of fluid flow through the main cavity at the largest inner circumference and through the openings based on the specific position of the occluding body within the main cavity. Further, Frazee et al does not teach that said at least one opening [114][116][118] is not aligned with any other said at least one opening with respect to a main axis of extension of the catheter body [90], since Frazee et al teaches that said openings are aligned with each other with respect to the main axis of the catheter body (Figure 4). Don Michael teaches a catheter (catheter [2]) comprising openings (openings [28][30]), wherein said openings are not aligned with the main axis of the catheter, since said openings are disposed in a helical fashion about the catheter (Figure 2). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the openings, of the catheter of Frazee et al, to be non-aligned with each other, as taught by Don Michael, as an obvious design choice to the user, since it has been held that rearranging parts (openings) of an invention involves only routine skill in the art. *In re Japikse, 86 USPQ 70.* Also, non-aligned openings will provide a wider area and direction of fluid flow, since the location of the openings is not restricted to one axis. *From Applicant's specification, the first occluding means is an*

inflatable element (page 8, lines 19-20), and the second occluding means is an occluding body and an insertion cable (page 9, lines 14-17).

In regards to claim 4, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, Frazee et al teaches that said first occluding means [41] comprises an inflatable element positioned round the catheter body [90] (Figure 4), said inflatable element [41], in a rest state, adhering substantially to the catheter body [90], and in a working state, being substantially in contact with the inner wall of the first vessel [72][74] (Figure 8) (column 3, lines 58-63).

In regards to claim 5, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, Frazee et al teaches that said inflatable element [41] is in fluid communication with the proximal end [30] so as to be operable from said proximal end (column 4, lines 62-67).

In regards to claim 6, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, Frazee et al teaches that said catheter body [90] comprises a secondary cavity (inflation lumen [105]), which extends from the proximal end [30] to the distal end [32] and is hermetically separated from said main cavity [101] (Figure 5), said secondary cavity [105] being in fluid connection with said first occluding means [41] so as to permit the actuation of said first occluding means (column 4, lines 59-67).

In regards to claim 7, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, Frazee et al teaches that said secondary cavity [105] is produced in a thickness of said lateral wall of said catheter body [90] (Figure 5).

In regards to claim 12, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, Frazee et al teaches that said catheter body [90], at said distal end [32], comprises a

portion with a tapered profile so as to reduce the cavity of the catheter body at the distal end (Figure 7).

In regards to claim 13, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, Frazee et al teaches that said second occluding means, at said distal end [32], comprises a membrane [127] suitable for at least partially occluding said main cavity [101] and having a hole (slit [130]) suitable for allowing the passage of the guide cable [18] of the catheter (Figure 7) (column 5, lines 29-35).

In regards to claim 15, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, Frazee et al does not state that the membrane [127] is made of a material suitable for being sterilized. However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide a sterilizable material for the membrane, since it was known in the art, as common practice in the art, to sterilize medical equipment, such as catheters, in order to eliminate transmissable agents (bacteria, viruses, etc.) from medical surfaces in order to prevent contamination to the environment.

In regards to claim 18, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, Frazee et al teaches a main pathway (connector [103]), at said proximal end [30], that is suitable for receiving said second occluding means [127] and is fluidly connected to said main cavity [101] (Figure 4) (column 4, lines 59-62).

In regards to claim 20, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, Frazee et al teaches that said proximal end [30] comprises a secondary pathway (connector [107]), fluidly connected to said secondary cavity [105], and suitable for receiving at

the inlet a fluid for allowing actuation of the first occluding means [41] (Figure 4) (column 4, lines 62-67).

In regards to claim 21, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, Frazee et al teaches that said proximal end [30] comprises am infusion pathway (connector [103]), fluidly connected to said main cavity [101] and suitable for receiving at the inlet a fluid, so as to allow the flow of the fluid from the proximal end [30] to the distal end [32] (Figure 4) (column 4, lines 59-62)(column 5, lines 20-28).

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazee et al, Briscoe et al, and Don Michael, as applied to claim 6 or 7 above, and further in view of Prosl (US 5,868,717).

In regards to claim 8, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, Frazee et al does not teach that said catheter body [90] has an oval cross-section with a first pole more pronounced than a second pole, since Frazee et al teaches that said catheter body has a circular cross-section (Figure 5). Prosl teaches a catheter [10] having an oval cross-section, wherein a first pole (second wall [30]) is more pronounced than a second pole (first wall [20] diametrically opposed to the first pole, and the first pole [30] receives the secondary cavity (second lumen [35]) (Figure 1B). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the cross-section of the catheter body, of the modified catheter of Frazee et al, Briscoe et al, and Don Michael, with an oval cross-section, as taught by Prosl, as an obvious design choice to the user, since regardless of the cross-sectional shape of the catheter, the catheter will function to perfuse a substance into a vessel and to inflate a first occluding means.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazee et al, Briscoe et al, and Don Michael, as applied to claim 1 above, and further in view of Thompson et al (US 3,827,434).

In regards to claim 10, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, neither Frazee et al nor Briscoe et al teaches that said occluding body is substantially spherical in shape. Thompson et al teaches a catheter (Figures 1-4, catheter assembly [14]), wherein an occluding body (spherical distal tip [51]) of an occluding means (stylet [51]) is substantially spherical in shape. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the occluding body of the second occluding means, of the modified catheter of Frazee et al, Briscoe et al, and Don Michael, to be substantially spherical in shape, as taught by Thompson et al, as a spherical occluding body will reduce the danger of the second occluding means tearing or piercing the catheter or patient's vessel (column 4, lines 29-34).

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazee et al, Briscoe et al, and Don Michael, as applied to claim 1 above, and further in view of McCoy (US 5,135,517).

In regards to claim 11, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, neither Frazee et al nor Briscoe et al teaches that said occluding body is substantially frustoconical in shape. McCoy teaches a catheter (Figures 6-10, core member [112]), wherein an occluding body (scraping blade [130]) of an occluding means (scraper [126]) is substantially

frustoconical in shape. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the occluding body of the second occluding means, of the modified catheter of Frazee et al, Briscoe et al, and Don Michael, to be substantially frustoconical in shape, as taught by McCoy, as an obvious design choice to the user, because regardless of the shape of the occluding body, such as cylindrical, spherical, or frustoconical, for example, the occluding body will function to at least partially occlude the main cavity to minimize fluid flow towards the open distal end of the catheter (Figure 8).

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazee et al, Briscoe et al, and Don Michael, as applied to claim 18 above, and further in view of Zhang (US 5,971,958).

In regards to claim 19, in a modified catheter of Frazee et al, Briscoe et al, and Don Michael, Frazee et al does not teach that said main pathway [103] comprises a threaded section capable of producing a threaded connection with a corresponding threaded portion of said second occluding means [127]. Zhang teaches a catheter with a main pathway (introducer hub, *not referenced*) comprising a threaded section capable of producing a threaded connection with a corresponding threaded portion of a second occluding means (obturator, *not referenced*) (column 10, lines 23-65). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide a threaded section on the main pathway and a threaded portion on the second occluding means, of the modified catheter of Frazee et al, Briscoe et al, and Don Michael, so that a threaded engagement, of the main pathway and the second occluding

body, will inhibit the rotational disengagement of the main pathway and the second occluding body (column 10, lines 23-65).

Response to Arguments

14. Applicant's arguments filed on June 9, 2010, have been fully considered but they are not persuasive:

In regards to claims 1, 25, and 31, in the combination of Frazee et al, Briscoe et al, and Don Michael, Applicant argues that neither Frazee et al nor Briscoe et al teaches the new limitation that the occluding body is in contact with the inner circumference of the main cavity where said inner circumference of said main cavity is at its largest (Reply, page 9). However, even though both Frazee et al and Briscoe et al teach an occluding body in an area of the main cavity that does not have the largest inner circumference, whether or not the occluding body contacts the largest inner circumference of the main cavity depends upon the diameter or size and flexibility of the occluding body. Briscoe et al teaches an occluding body that is flexible such that the occluding body can pass through areas of the main cavity having different inner circumferences (page 10, lines 1-7). Hence, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the occluding body, of the modified catheter of Frazee et al and Briscoe et al, to be larger in diameter or more flexible to contact the inner circumference of the main cavity at its largest, as a matter of obvious design choice, since modifying the size and flexibility of materials, such as occluding bodies, are well-known in the art. Furthermore, modifying the occluding body to a size and flexibility that would contact the inner circumference of the main cavity at its largest would allow for the regulation

and direction of fluid flow through the main cavity at the largest inner circumference and through the openings based on the specific position of the occluding body within the main cavity.

Applicant argues that there is no motivation or suggestion to combine Frazee with Briscoe since if the insertion cable of Briscoe is fixed to the second occluding means of Frazee, the utility and/or functionality of such second occluding means would be destroyed as a guidewire could no longer be inserted through the slit (Reply, page 10). Examiner disagrees. The resultant second occluding means of Frazee and Briscoe is capable of having both a slit within the occluding body for the passage of a guidewire and an insertion cable for adjusting the position of the occluding body within the main cavity.

Applicant disagrees with the motivation to combine Frazee with Briscoe (Reply, pages 10-11). The insertion cable of Briscoe will allow the user the ability to control the depth of the occluding body. Even though Frazee already teaches preventing or allowing fluid to flow through the openings of the catheter, the insertion cable will allow for the change in position of the occluding body within the main cavity such that the user can control which openings can or cannot fluidly communicate with other openings. For example, in the combination of Frazee and Briscoe, if the occluding body is adjustably positioned in between opening [112] and opening [116], then the portion of the lumen proximal to and including the opening [112] cannot fluidly communicate with the portion of the lumen distal to and including the opening [116]. The substance to be perfused would then only flow through a select number of openings.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
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08/04/2010

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